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To: **Examiner V. Ford**
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Group Art Unit: **1645**

Message/Comments: **Proposed Claim Amendments.**

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DRAFT AMENDMENT - FOR DISCUSSION PURPOSES ONLY
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Nuijten et al.

Serial No.: 09/749,025

Filed: December 27, 2000

For: SALMONELLA VACCINE

Examiner: V. Ford

Group Art Unit: 1645

Attorney Docket No.: 2990 - 5048US

Proposed Claim Amendments

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed August 12, 2004, applicants submit the following proposed amendments for discussion with the Examiner.

Proposed Amendments to the Claims are reflected in the listing which begins on page 2 of this paper.

IN THE CLAIMS:

Applicants propose to amend claims 7, 10, 11, 19 through 24, and 27 through 29, cancel claims 8, 9, 25 and 26 and add new claims 30 to 34. Claims 1 to 6 and 12 to 18 were previously canceled.

Listing of Claims:

Claims 1 to 6 (Canceled).

7. (Currently amended) A ~~marker vaccine~~ method for marking exposure of a subject to wild-type *Salmonella*, the method comprising administering an immunologically effective amount of a mutated bacterium and a pharmaceutically acceptable carrier to a subject, said mutated bacterium being selected from the group consisting of the *Salmonella* species *typhimurium, enteritidis, choleraesuis, dublin, abortus-ovi, abortus-equi, derby, hadar, heidelberg, agona,* and *arizonae,* that in its wild type form carries flagella, said mutated bacterium ~~lacking~~ not capable of inducing an immune response to flagellin due to a mutation in a gene of the flagellar biogenesis pathway, said bacterium being in live attenuated form.

8. (Canceled).

9. (Canceled).

10. (Currently amended) The ~~marker vaccine~~ method according to claim 7, ~~comprising~~ wherein administering an immunologically effective amount of a mutated bacterium and a pharmaceutically acceptable carrier to a subject further comprises administering an adjuvant to the subject.

11. (Currently amended) The ~~marker vaccine~~ method according to claim 7, wherein administering an immunologically effective amount of a mutated bacterium and a pharmaceutically acceptable carrier to a subject comprises administering an immunologically effective amount of a mutated bacterium and a pharmaceutically acceptable carrier in a freeze-dried or spray-dried form.

Claims 12 to 18 (Canceled).

19. (Currently amended) ~~A marker vaccine~~ An immunogenic composition for marking exposure of a subject to wild-type *Salmonella*, comprising an immunologically effective amount of a mutated bacterium, ~~and~~ a pharmaceutically acceptable carrier, and an adjuvant, said mutated bacterium being selected from the group consisting of the *Salmonella* species *typhimurium, enteritidis, choleraesuis, dublin, abortus-ovi, abortus-equi, derby, hadar, heidelberg, agona,* and *arizonae,* that in its wild type form carries flagella, said mutated bacterium lacking at least one antigenic determinant of flagellin and not being capable of inducing an immune response to flagellin due to a mutation in a gene of the flagellar biogenesis pathway ~~or flagella found in its wild type form,~~ and said mutated bacterium being inactivated.

20. (Currently amended) A ~~vaccine~~ method for ~~the protection of~~ protecting animals against Salmonellosis strains, the method comprising:

administering to an animal a vaccine comprising:

an immunologically effective amount of a mutated *Salmonella typhimurium* bacterium that in its wild type form carries flagella, said mutated *Salmonella typhimurium* bacterium ~~lacking~~ not capable of inducing an immune response to flagellin due to a mutation in a gene of the flagellar biogenesis pathway, and

a pharmaceutically acceptable carrier.

21. (Currently amended) ~~The~~ A vaccine ~~of claim 20, wherein the~~ for the protection of

animals against Salmonellosis strains, comprising:

an immunologically effective amount of a mutated *Salmonella typhimurium* bacterium that in its wild type form carries flagella, said mutated *Salmonella typhimurium* bacterium lacking flagellin~~, comprises~~ and comprising an immunologically effective amount of a *Salmonella typhimurium* strain STMP mutated bacterium, and

a pharmaceutically acceptable carrier.

22. (Currently amended) An improved method for protecting animals against Salmonellosis strains, by administering ~~*Salmonella* vaccine, having~~ an immunologically effective amount of a *Salmonella* bacterium and a pharmaceutically acceptable carrier to an animal, the improvement comprising ~~the~~ :

administering to the animal a live attenuated *Salmonella* bacterium ~~being~~ which bacterium is a mutated bacterium that in its wild type form carries flagella, but in its mutated form is no longer capable to induce ~~antibodies against at least one antigenic determinant of~~ an immune response to flagellin ~~or flagella~~ in the animal, said mutated bacterium including a mutation in a gene of the bacterium's flagellar biogenesis pathway.

23. (Currently amended) The improved ~~*Salmonella* vaccine~~ method of claim 22, wherein ~~the~~ administering a *Salmonella* bacterium which is a mutated bacterium comprises administering a mutated bacterium ~~is~~ selected from the group consisting of the *Salmonella* species *typhimurium, enteritidis, choleraesuis, dublin, abortus-ovi, abortus-equi, derby, hadar, heidelberg, agona,* and *arizonae*.

24. (Currently amended) The improved ~~*Salmonella* vaccine~~ method of claim 22, wherein ~~the~~ administering a *Salmonella* bacterium which bacterium is a mutated bacterium comprises administering a mutated bacterium that lacks flagellin.

25. (Canceled).

26. (Canceled).

27. (Currently amended) The improved ~~*Salmonella* vaccine~~ method of claim 22, further comprising co-administering an adjuvant.

28. (Currently amended) The improved ~~*Salmonella* vaccine~~ method of claim 22, wherein administering a *Salmonella* bacterium which bacterium is a mutated bacterium comprises administering the mutated bacterium in a freeze-dried or spray-dried form.

29. (Currently amended) ~~A~~ An improvement in a marker vaccine, ~~consisting of~~ comprising a *Salmonella* bacterium, the improvement comprising:

an immunologically effective amount of a mutated bacterium that in its wild type form carries flagella, said mutated bacterium ~~lacking~~ not capable of inducing an immune response to flagellin due to a mutation in a gene of the flagellar biogenesis pathway and being selected from the group consisting of the *Salmonella* species *typhimurium, enteritidis, choleraesuis, dublin, abortus-ovi, abortus-equi, derby, hadar, heidelberg, agona,* and *arizonae,* the mutated bacterium being inactivated;

an adjuvant; and

a pharmaceutically acceptable carrier.

30. (New) The immunogenic composition according to claim 19 in a freeze-dried or spray-dried form.

31. (New) The improved marker vaccine of claim 29, wherein the mutated bacterium lacks flagellin.

32. (New) The improved marker vaccine of claim 29, in a freeze-dried or spray-dried form.

33. (New) In an immunogenic composition including a *Salmonella* bacterium, the improvement comprising:

the immunogenic composition comprising an inactivated mutated *Salmonella* bacterium, said *Salmonella* bacterium selected from the group consisting of the *Salmonella* species *typhimurium, enteritidis, choleraesuis, dublin, abortus-ovi, abortus-equi, derby, hadar, heidelberg, agona,* and *arizonae,* said *Salmonella* bacterium in its wild type form carrying flagella, said mutated *Salmonella* bacterium lacking at least one antigenic determinant of flagellin and not being capable of inducing an immune response to flagellin due to a mutation in a gene of the flagellar biogenesis pathway, and an adjuvant.

34. (New) The improved immunogenic composition according to claim 36 in a freeze-dried or spray-dried form.